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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/514,955	02/28/2000	Stephen Paul Bryant	1581.059000/RWE	8701

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EXAMINER

MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/02/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/514,955

Applicant(s)

BRYANT ET AL.

Examiner

Channing S. Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Attachment for PTO-948*.

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### **DETAILED ACTION**

#### *ART UNIT DESIGNATION*

The Group and/or Art Unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence regarding this application should be directed to Group Art Unit 1631.

#### *OBJECTION BY DRAFTSMAN*

Applicants are hereby notified that the required timing for correction of drawings has changed. See the last 6 lines on the sheet, which is attached, entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". Due to the above notification Applicant is required to submit drawing corrections with the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

### **Restriction/Election Requirement**

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-13, drawn to a database comprising plurality of records, classified in class 702, subclass 19. If this group is elected, then the below summarized specie election is also required.
- II. Claim 14, drawn to a method of adding information to a database, classified in class 702, subclass 19.
- III. Claim 15, drawn to a method of identifying a correlation between phenotype information and genotype information utilizing a database, classified in class 702, subclass 19.

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- IV. Claim 16, drawn to a method of identifying a correlation between first phenotype information and second phenotype information utilizing a database, classified in class 702, subclass 19.
- V. Claim 17, drawn to a method of identifying a correlation between genotype information and genotype information utilizing a database, classified in class 702, subclass 19.
- VI. Claim 18, drawn to a method of allocating priority to a candidate gene or locus utilizing a database, classified in class 702, subclass 19.
- VII. Claim 19, drawn to a method of analyzing the relation between a genotype and a phenotype utilizing a database, classified in class 702, subclass 19.
- VIII. Claim 20, drawn to a method of determining the capacity and specificity of a genetic marker to detect and quantify normal variations in healthy and affected populations for a selected risk trait utilizing a database, classified in class 702, subclasses 19 and 20.
- IX. Claim 21, drawn to a method of devising dose regimes and/or dose forms and/or drug delivery systems for a given drug in a clinical trial utilizing a database, classified in class 702, subclass 19.
- X. Claim 22, drawn to a method of predicting response to a proposed drug therapy utilizing a database, classified in class 702, subclass 22.
- XI. Claim 23, drawn to a method of correlating genotype and phenotype information with account taken of potential or actual confounding information utilizing a database, classified in class 702, subclass 19.

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- XII. Claim 24, drawn to a method of diagnosing disease or predisposition to disease in an individual not showing significant signs of disease utilizing a database, classified in class 702, subclass 19.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the database of Group I can be utilized in the distinct processes of Groups II-XII. Invention II is directed to a method of adding information to a database. Invention III is directed to a method of identifying a correlation between phenotype information and genotype information utilizing a database. Invention IV is directed to a method of identifying a correlation between first phenotype information and second phenotype information utilizing a database. Invention V is directed to a method of identifying a correlation between genotype information and genotype information utilizing a database. Invention VI is directed to a method of allocating priority to a candidate gene or locus utilizing a database. Invention VII is directed to a method of analyzing the relation between a genotype and a phenotype utilizing a database. Invention VIII is directed to a method of determining the capacity and specificity of a genetic marker to detect and quantify normal variations in healthy and affected populations for a selected risk trait utilizing a database. Invention IX is directed to a method of devising dose regimes and/or dose forms and/or drug delivery systems for a given drug in a clinical trial utilizing a database. Invention X is directed to a method of predicting response to a proposed

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drug therapy utilizing a database. Invention XI is directed to a method of correlating genotype and phenotype information with account taken of potential or actual confounding information utilizing a database. Invention XII is directed to a method of diagnosing disease or predisposition to disease in an individual not showing significant signs of disease utilizing a database. It is acknowledged that the above inventions are classified within the same class and subclass, however such classification does not exclude such inventions from restriction since it is shown that each invention contains divergent subject matter, and are distinctly different processes.

Inventions II-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04, M.P.E.P. § 808.01). It is acknowledged that Groups II-XII all utilize a database, however all the inventions are drawn to differing methodologies which are comprised of different operational steps and therefore have different results. Thus, Groups II-XII are distinct methods and further justifies the distinctness of Group I and Groups II-XII.

*SPECIES ELECTION REQUIREMENT APPLICABLE ONLY IF GROUP I IS ELECTED*

This application contains claims directed to the following patentably distinct species of the claimed invention:

- IA. DNA sequence, claim 13
- IB. variation between sequences, claim 13
- IC. sequence length, claim 13

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Currently, claims 1-13 are generic to the above Species IA-IC. The following are definitions to the above distinct species, which justifies and forms the basis of the species election requirement: IA. DNA sequence represented by A (adenine), G (guanine), C (cytosine), and T (thymine) bases; IB. characteristic or value representative of the differences between sequences; and IC. numerical value representing sequence length. The above species are distinct types of information utilized in a database and thus establishes the search burden for the above species as non-overlapping, which documents this species election requirement due to an undue search burden that would exist if the search for the prior art covered these non-overlapping species together.

Applicants are required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

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Should applicants traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

#### *INVENTORSHIP AMENDMENT*

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

#### *EXAMINER INFORMATION*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *July 1, 2002*

Examiner Initials: *CSM*

*Ardin H. Marschel*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER

**Attachment for PTO-948 (Rev. 03/01, or earlier)**  
**6/18/01**

**The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.**

**INFORMATION ON HOW TO EFFECT DRAWING CHANGES**

**1. Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

**2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

**Timing of Corrections**

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.